K082257

WIELAND

WIELAND Dental + Technik
GmbH & Co. KG
Schwenninger Straße 13
75179 Pforzheim, Germany
Postfach 10 20 40
75120 Pforzheim, Germany
Fon +49 72 31 / 37 05-0
Fax +49 72 31 / 35 79 59

SEP 1 8 2008

7. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
Schwenninger Str. 13
D-75179 Pforzheim
Germany
Phone: +49-7231-3705-0

Contact person: Dr. Gerhard Polzer
Phone: +49–7231–3705–219
Fax: +49-7231-357959
e-mail: gerhard.polzer@wieland-dental.de

Date of Summary: 2008-07-03

Trade name: ZENO Al eco Disc

Classification name: Powder, Porcelain
Product code: EIH
C.D.R section: 872.6660
Classification: Class II

Legally marketed equivalent device: inCoris AL

510(k) number: K062506

WIELAND

WIELAND Dental+Technik
GmbH & Co. KG
Schwenninger Straße 13
75179 Pforzheim, Germany
Postfach 10 20 40
75120 Pforzheim, Germany
Fon +49 /2 31/ 37 05-0
Fax +49 /2 31/ 35 79 59

510 (k) Summary

Device description

ZENO Al eco Discs are milling blanks composed of pure aluminium oxide. They are intended to be used by professional dental technicians for making single copings and primary components for anteriors and premolars to apply them as ceramic frameworks for dental prosthetics for the sole use of particular patients.

ZENO Al eco Discs can be machined in all machines of the ZENO Tec system. The manufacturing process of this ceramic framework consists of different steps. At first the model has to be scanned. In the next step, the restoration has to be designed virtually with the help of the CAD technology. Thereafter, the realization of this design has to be carried out by the CAM technology. In a final step after hard sintering of the ZENO Al eco, the framework can be veneered with a suitable veneering ceramic.

Recommended application

With the introduction of the ZENO Al eco Discs, Wieland Dental+Technik offers to the customer for the ZENO TEC System the possibility to produce high aesthetic single copings and primary components on the base of Aluminium oxide. This kind of restoration is cost- and time saving and the restorations have excellent properties.

Comparison with the predicate device

ZENO Al eco Discs are substantially equivalent to the dental device inCoris AL. Both devices based on Aluminium oxide and have similar indications for use and comparable physical, biological, and chemical properties.

Due to the excellent material properties of the ZENO Al eco Discs, the restorations possess a high-level safety and effectiveness. ZENO Al eco Discs therefore are as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2008

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Company KG
Schwenninger Straße 13
75179 Pforzheim, Germany

Re: K082257
Trade/Device Name: ZENO AI eco Disc
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 4, 2008
Received: August 8, 2008

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WIELAND

WILLAND Dental + Technik
GmbH & Co. KG
Schwenninger Straße 13
75179 Pforzheim, Germany
Postfach 10 20 40
75120 Pforzheim, Germany
Fon +49 72 31/ 37 05-0
Fax +49 72 31/ 35 79 59

12.8. Indication for use statement

Indications for Use

510(k) Number (if known): K082257

Device Name: ZENO Al eco Disc

Indications for Use:

ZENO® Al eco Discs are milling blanks from which single copings and primary components for anteriors and premolars can be made.
These are intended for use as ceramic frameworks for dental prosthetics..

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082257

(Posted November 13, 2003)